Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Claim 3 has been amended to even more clearly define the structure of the flow control means feature of the device. The written description portion of the specification has been amended as required by the examiner. New claims 21-23 have been added to further define the scope of protection sought for Applicants' invention. Claims 1 and 3-23 are now pending in the application, with claims 12-19 withdrawn from consideration as being directed to a non-elected invention. Claims 1, 12, and 21 are independent. The objections and rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments. Entry of each of the amendments is respectfully requested.

As indicated above, specification page 5 has been amended to rephrase the heading as "BRIEF DESCRIPTION OF THE DRAWING." The heading, therefore, fully complies with the requirements of both 37 CFR § 1.77(b)(8) ("Arrangement of application elements") and MPEP § 608.01(a) ("Arrangement of Application"). Accordingly, reconsideration and withdrawal of the objection to the disclosure are respectfully requested.

Applicants note that the Office Action still indicates that the drawing is objected to by the examiner (Office Action page

2, numbered paragraph 4). The Office Action asserts that "[t]he flow control means appears to be some type of a controller."

Applicants again submit that the aforementioned ground of objection is in error. For all of the reasons presented in Applicants' Amendment filed June 24, 2009, and during the personal interview of June 30, 2009, Applicants submit that the sole drawing figure is fully compliant. First, as explained in the aforementioned Amendment, the drawing figure *does* show, as required, every feature of the invention specified in the claims. Claim 3 depends from claim 1. The drawing figure depicts the claimed "flow control means" (i.e., the illustrated elements 36, 38, 40, and 42). See, e.g., Applicants' disclosure at specification page 6, the paragraph beginning with "[v]alve means." Applicants disclose that "[v]alve means, *typically consisting of hose clamps*, identified with reference numerals 36, 38, and optionally 40 are provided, respectively on tubing sections 34, 16c, and 28b; optionally, valve means consisting of a *hose clamp* 42 may also be provided on tubing section 28a" (emphasis added).

Applicants respectfully submit that any person skilled in the art would recognize that the disclosed "valve means" is a "flow control means." Applicants even disclose that "said valve means are adapted to *cut off flow* in the corresponding tubing sections" (specification page 6). Accordingly, since the drawing figure *does* depict each of elements 36, 38, 40, and 42, the drawing figure *does*

show, as required, every feature of the invention specified in the claims. Reconsideration and withdrawal of the aforementioned objection to the drawing are respectfully requested.

Applicants also again submit that the additional ground of objection to the drawing (Office Action page 3, numbered paragraph 5) is in error. As also explained in the aforementioned Amendment and during the interview, the sole drawing figure fully complies with the provisions of 37 CFR § 1.84(u)(1). In fact, *no legend is allowed* because § 1.84(u)(1) requires that "[w]here only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation 'FIG.' *must not appear*" (emphasis added).

During the interview the examiner took the revised position that while perhaps the abbreviation "FIG." should not appear, the provisions of § 1.84(u)(1) mean that the *word* "Figure" must appear. Applicants' representative respectfully disagreed with the examiner's position.

To resolve this issue, Applicants' representative telephoned the USPTO Inventor Assistance Center on June 30, 2009. The USPTO representative agreed with Applicants' above-stated understanding of the rules, i.e., that *no legend is allowed* under § 1.84(u)(1), stating "[t]hat is correct." The USPTO representative advised the Applicants to "just quote the rule to the examiner."

Accordingly, the provision of 37 CFR § 1.84(u)(1) has been quoted herein, and reconsideration and withdrawal of the aforementioned objection to the drawing are respectfully requested. Correction of the Office Action Summary in the next communication from the USPTO is again respectfully requested.

35 U.S.C. § 103(a) - Stewart and Gsell

Claims 1, 3, 4, 7, and 9-11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,128,048 to Stewart et al. (hereinafter "Stewart") in view of U.S. Patent No. 5,258,127 to Gsell et al. ("Gsell"). The examiner acknowledges that Stewart fails to disclose Applicants' claim 1 feature of "a leukocyte filter being configured to filter leukocytes and to allow platelets to pass therethrough" (Office Action page 5).

The rejection of claims 1, 3, 4, 7, and 9-11 under § 103(a) based on Stewart and Gsell is respectfully traversed. For at least the following reasons, the combined disclosures of Stewart and Gsell would not have rendered obvious Applicants' claimed invention.

First, the combined disclosures of Stewart and Gsell do not teach each feature of Applicants' claimed invention. As the examiner has acknowledged, Stewart fails to disclose Applicants' claim 1 feature of "a leukocyte filter being configured to filter leukocytes and to allow platelets to pass therethrough." Stewart

is also deficient in other respects, as explained in detail in Applicants' Amendment filed June 24, 2009.

To rectify the acknowledged deficiency of Stewart, the examiner relies upon the disclosure of Gsell. But regardless of what Gsell may disclose with regard to a "Leucocyte Depleting Filter Device," Gsell simply fails to rectify *other deficiencies* of Stewart.

Stewart's system is structurally and functionally different from Applicants' claimed device that separates blood into blood components. By way of review, claim 1 defines a device that includes, *inter alia*, "a second satellite container being connected to said collecting container through a conduit means that bypasses said filter, said flow control means being configured to allow fluid flow from said second satellite container into said collecting container only through said conduit means that bypasses said filter." That is, as depicted in Applicants' drawing figure, the claimed device includes a second satellite container 6 being connected to the collecting container 2 *through a conduit means 34 that bypasses the filter 22*, the flow control means 42 being configured to allow fluid flow from the second satellite container 6 into the collecting container 2 *only through the conduit means 34 that bypasses the filter 22*.

That is, even more specifically, one structural difference between Stewart's disclosure and Applicants' device is found in Applicants' tubing section 28a in which valve means 42 is

located. By closing valve means 42, the leukocyte filter 22 is bypassed, but fluid communication is maintained between the second satellite container 6 and the collecting container 2. At the same time, fluid communication between the collecting container 2 and the first satellite container 4 via the filter 22 is established.

Stewart fails to teach this structural and functional feature of Applicants' claimed device. A device in which a single flow control device is operable in such a variable way represents a substantial operational advantage over the system taught by Stewart.

And, Gsell's disclosure adds nothing that would rectify this deficiency of Stewart. Therefore, the asserted Stewart/Gsell combination fails to disclose each feature of Applicants' claimed invention.

Second, there is simply no teaching in either Stewart or Gsell that would have led one to select the references and combine them in a way that would produce the various embodiments of the invention defined by any of Applicants' pending claims. For example, a person having ordinary skill in the art would not have found motivation in Stewart to consider the disclosure of Gsell, because a separation of whole blood into PRP and PRC is simply not the subject of Stewart's disclosure.

In response to the examiner's comments regarding "intended use," claim 3 has been amended to even more clearly define the structure of the flow control means feature of the

device in order to advance prosecution. The "adapted to" language has been deleted from claim 3.

However, as urged previously, Applicants also submit that the assertion that the claim language represents an "intended use" of the filter reflects an unreasonably narrow interpretation of both the claim language and the relevant legal authority. Clearly, Applicants' specification defines the filter as being a "leukocyte filter." At specification page 22, Applicants even disclose that the filter device 22 has porous elements "specifically adapted for leukocyte removal." Applicants submit that the general structure and operating principles of a leukocyte filter are well known to one skilled in the relevant art.

Furthermore, Applicants' specification also clearly defines the object of the claimed device, i.e., "to remove *leukocytes* from the generated components" (specification page 1, second paragraph). Therefore, by virtue of *removing leukocytes*, the filter provides the "leukocyte depleted platelet rich plasma component (PRP)" and the "leukocyte depleted packed red cells component (PRC)."

Accordingly, the combined disclosures of Stewart and Gsell would not have rendered obvious the invention defined by Applicants' claim 1. Claims 3, 4, 7, and 9-11 are allowable because they depend, either directly or indirectly, from claim 1, and for the subject matter recited therein.

35 U.S.C. § 103(a)

Since the Stewart/Gsell combination is applied in each of the other rejections under § 103(a)[1] -- claims 5, 6, and 20 as being unpatentable over Stewart and Gsell in view of WO 03/063930 to Corbin et al. ("Corbin"), and claim 8 as being unpatentable over Stewart and Gsell in view of U.S. Patent No. 7,264,608 to Bischof et al. ("Bischof") -- each of these rejections is also respectfully deemed to be obviated. The combined disclosures of the cited references would not have rendered obvious Applicants' presently claimed invention because the disclosures of the additional references do not rectify any of the above-described deficiencies of the Stewart/Gsell combination.

Furthermore, there is simply no teaching in any of the references that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' presently pending claims.

Therefore, the various combinations of references would not have rendered obvious the invention defined by any of Applicants' presently pending claims.

New claims 21-23 have been added to further define the scope of protection sought for Applicants' invention. New claims

1 Applicants note that claims 5, 6, and 20, and claim 8, stand rejected as being unpatentable, respectively, over "Stewart et al as applied to claim 1" (Office Action page 6, numbered paragraph 8) and "Stewart et al as applied to claim 4" (Office Action page 7, numbered paragraph 9). Applicants presume that the examiner intended to rely upon the Stewart/Gsell combination.

21-23 are also allowable. Claim 21 defines an embodiment of the device that includes in pertinent part "a plurality of valves that selectively control fluid flow associated with the collecting container, the first satellite container, and the second satellite container; and a bypass conduit that bypasses the leukocyte filter and that maintains the fluid communication between the collecting container and the second satellite container." Claim 21 also requires that "one of the plurality of valves [is] configured to provide for fluid flow from the second satellite container into the collecting container only through the bypass conduit." That is, as depicted in the drawing figure, one of the valves 42 is configured to provide for fluid flow from the second satellite container 6 into the collecting container 2 only through the bypass conduit 34.

Since independent claim 21 includes at least the features discussed above with respect to the rejection over the Stewart/Gsell combination, the references neither anticipate nor would have rendered obvious the device defined by claim 21.

Dependent claims 22 and 23 are also allowable. Claim 22 requires "a three-way conduit connector in the second satellite container conduit, wherein the valve that provides for fluid flow from the second satellite container into the collecting container only through the bypass conduit is located in the second satellite container conduit between the leukocyte filter and the three-way conduit connector." That is, again with reference to the drawing figure, the three-way conduit connector 30 is in the second

satellite container conduit 28a, 28b. And, the valve 42 that provides for fluid flow from the second satellite container 6 into the collecting container 2 only through the bypass conduit 34 is located in the second satellite container conduit 28a between the leukocyte filter 22 and the three-way conduit connector 30. By virtue of the claimed configuration, a single valve provides for flow both from the second satellite container 6 into the collecting container 2, and from the collecting container 2, through the leukocyte filter 22, and into the first satellite container 4. The asserted Stewart/Gsell combination provides no device with such operational flexibility.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that another interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: John C. Kuo Reg. No. 34,378
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N. W.
Washington, D.C. 20004
Telephone: (202) 638-6666
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